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Declaration of Gregg B. Fields Applicant(s): FIELDS et al. Serial No.: 09/529,691 Filed: 29 August 2000

For: INHIBITION OF TUMOR CELL ADHESION TYPE IV COLLAGEN

PATENT Docket No. 110.00680101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): FIELDS et al.)	Group Art Unit:	1642
Serial No.:	09/529,691)	Examiner:	S. L. Rawlings
Confirmation No.: 3203)		·
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Filed:	29 August 2000)		
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For: INHIBITION OF TUMOR CELL ADHESION OF TYPE IV COLLAGEN

DECLARATION OF GREGG B. FIELDS

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

- I, Gregg B. Fields, declare and say as follows:
- 1. I am a co-inventor of the subject matter claimed in the above-identified U.S. Patent Application Serial No. 09/529,691, filed August 29, 2000.
- 2. I received a Ph.D. in Chemistry from Florida State University in 1988. I was employed from 1991 to 1997 as a Professor at the University of Minnesota in the Department of Laboratory Medicine and Pathology and the Department of Biochemistry. I was also the Director of the Peptide Design and Synthesis Laboratory of the Biomedical Engineering Center at the University of Minnesota. I have been employed as a Professor at Florida Atlantic University

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in the Department of Chemistry and Biochemistry and the Department of Biomedical Science since 1997, and have been the Chair of the Department of Chemistry and Biochemistry since 2000. I am currently a consultant on peptide chemistry for Peptisyntha/Solvay. My research activities have included extracellular matrix biochemistry, synthetic protein design and construction, tumor cell biology, biomimetic biomaterials, proteases of the extracellular matrix, and solid-phase peptide syntheses methodology. I have authored over 150 articles and chapters in the area of biological chemistry and have presented over 90 seminars and lectures.

- 3. I have read and am familiar with the Office Action mailed December 3, 2002, with respect to the above-identified application and Knutson et al., "A type IV collagen-derived synthetic peptide, IV-H1, interacts with human melanoma CD44/chondroitin sulfate proteoglycan and inhibits invasion of basement membranes," Abstract 407, 86th Annual Meeting of the American Association for Cancer Research, Toronto, March 18-22, 1995 (hereinafter Abstract 407), a publication having been cited by the Examiner in the December 3, 2002 Office Action and which I co-authored. I hereby make this Declaration in support of the patentability of the claims of application Serial No. 09/529,691.
- 4. The D-enantiomer of IV-H1 disclosed in Abstract 407 is not the same polypeptide that is recited in 4 of the present application. The claimed polypeptide has the sequence gly-val-lys-gly-asp-lys-gly-asn-pro-gly-trp-pro-gly-ala-pro. The polypeptide referred to as the D-enantiomer of IV-H1 in Abstract 407, however, included a tyrosine at the end of the sequence. That is, the D-enantiomer of IV-H1 referred to in Abstract 407 had the sequence gly-val-lys-gly-asp-lys-gly-asn-pro-gly-trp-pro-gly-ala-pro-tyr. Although the nomenclature is the same as in the present application, at the time of publication of the Abstract 407, the sequence of the D-IV-

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H1 polypeptide referred to in Abstract 407 included a tyrosine. This is evidenced by the accompanying Exhibit A (Berndt et al., "Synthetic Lipidation of Peptides and Amino Acids: Monolayer Structure and Properties," *Journal of the American Chemical Society, 117*:9515, (1995) at page 9522, column 2, lines 41-42), which clearly shows the presence of the tyrosine residue. Although Berndt et al. (Exhibit A), at page 9519, column 2, lines 17 and 38 refer to IV-H1 as having 15 amino acids, this refers to the 15 amino acid sequence of IV-H1 without regard for the presence of the tyrosine residue. At the time, the D-IV-H1 polypeptide of Abstract 407 included the tyrosine residue for diagnostic purposes. Thus, Abstract 407, which does not disclose a specific sequence, refers to a polypeptide that does not have the same sequence as that claimed in the present invention.

5. I further declare that statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

April 3, 2003

Date

Grego R Fields Ph I